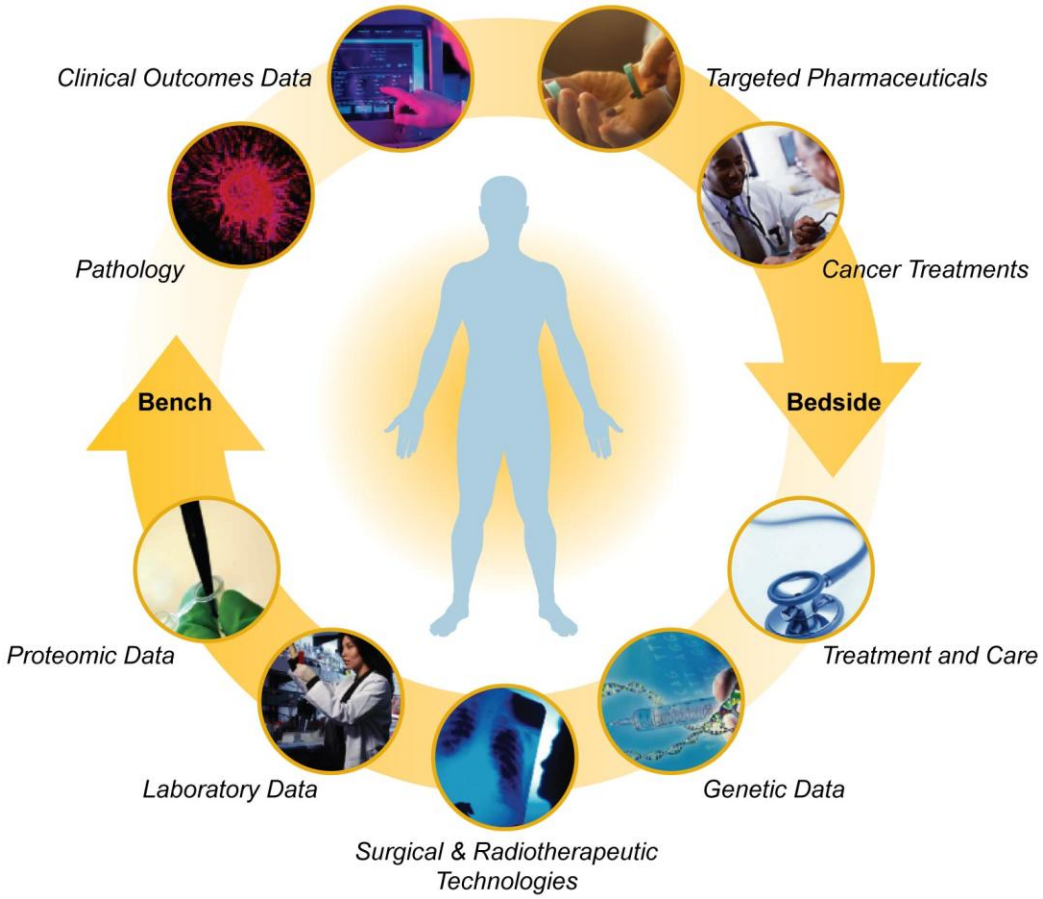
caBIG®
cancer Biomedical Informatics Grid®

A Transformation in Cancer Biomedical Informatics with caBIG®: How this may influence FDA

Kenneth H. Buetow, Ph.D.
National Cancer Institute

Personalized Medicine: What We're Trying to Achieve



- **Predictive, Preemptive, Participatory……**
- **Unifies clinical research, clinical care, and discovery (bench-bedside-bed) into a seamless continuum**
- **Results in improved clinical outcomes**
- **Accelerates the time from discovery to patient benefit**
- **Enables a health care system, not a disparate "sector"**
- **Empowers consumers in managing their health over a lifetime**

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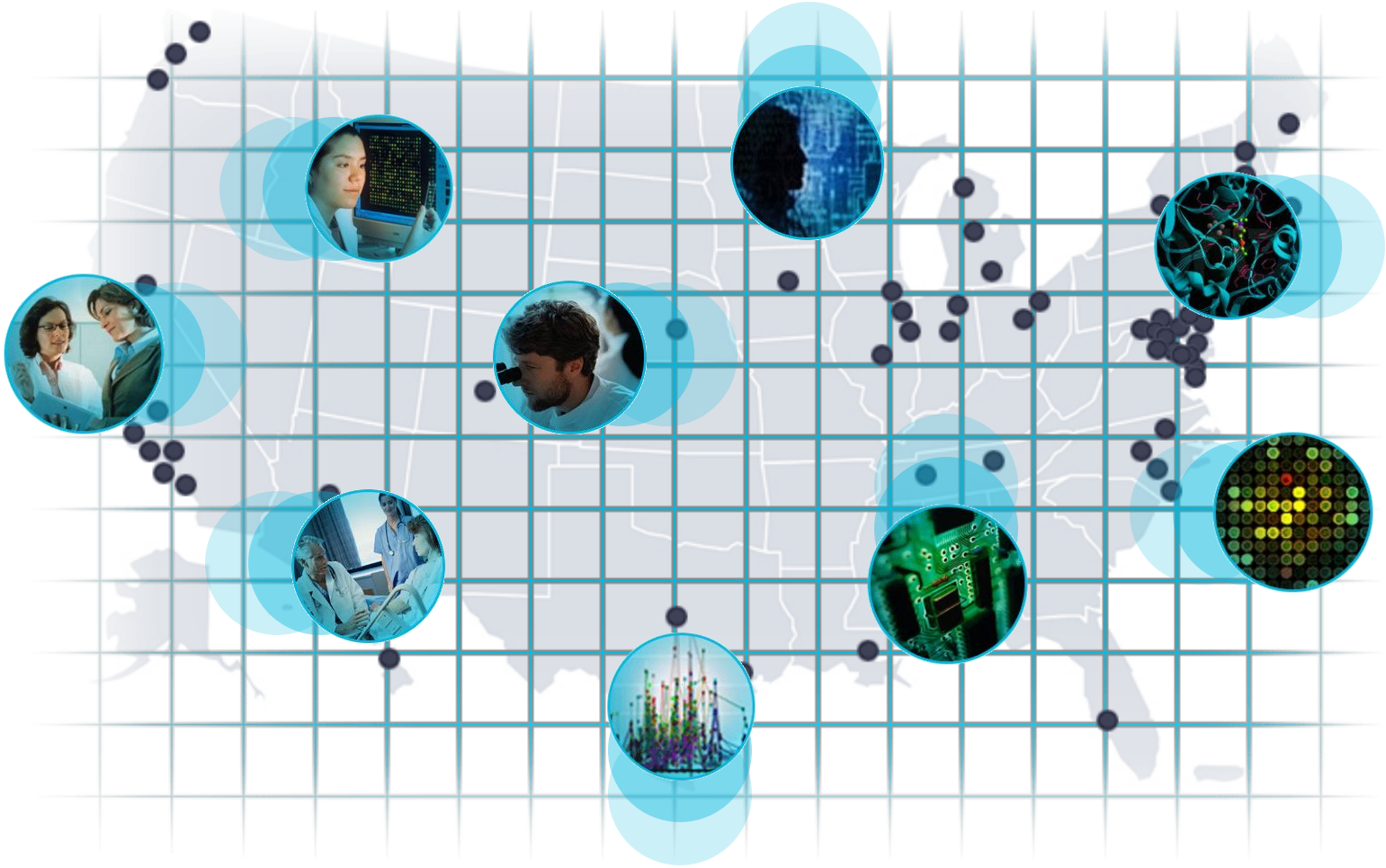
Molecular Medicine as a Complex Continuum

Molecular Medicine

Challenges:
The Biomedical Landscape

- **Isolated information “islands”**
- **Information dissemination uses models recognizable to Gutenberg**
- **Pioneered by Royal Academy of Science of London in the 17th century**
  - Write manuscripts
  - “Publish”
  - Exchange information at meetings

NCI is Utilizing Informatics to Integrate Cancer Information



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Cancer Biomedical Informatics Grid (caBIG®): Providing the IT "Glue"

The caBIG® Initiative

caBIG® is an information network enabling all constituencies in the cancer community – researchers, clinicians, patients – to share data and knowledge to accelerate the discovery of new diagnostics and therapeutics, and improve patient outcomes.

caBIG® Vision

- **Connect** the cancer research community through a shareable, interoperable infrastructure
- **Deploy and extend** standard rules and a common language to more easily share information
- **Build** or adapt tools for collecting, analyzing, integrating and disseminating information associated with cancer research and care

A Common Healthcare Infrastructure

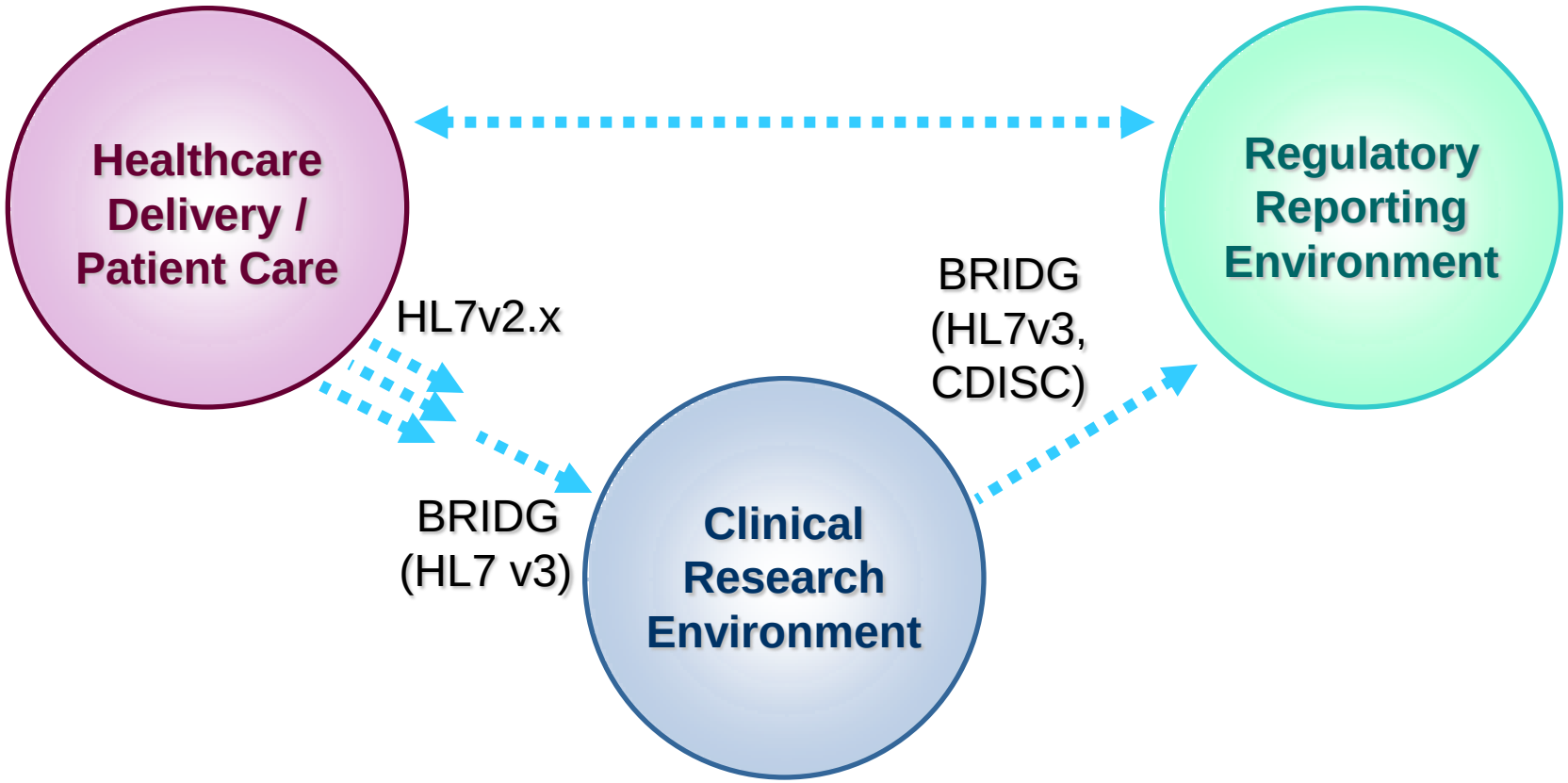
Healthcare Delivery / Patient Care

Regulatory Reporting Environment

Clinical Research Environment

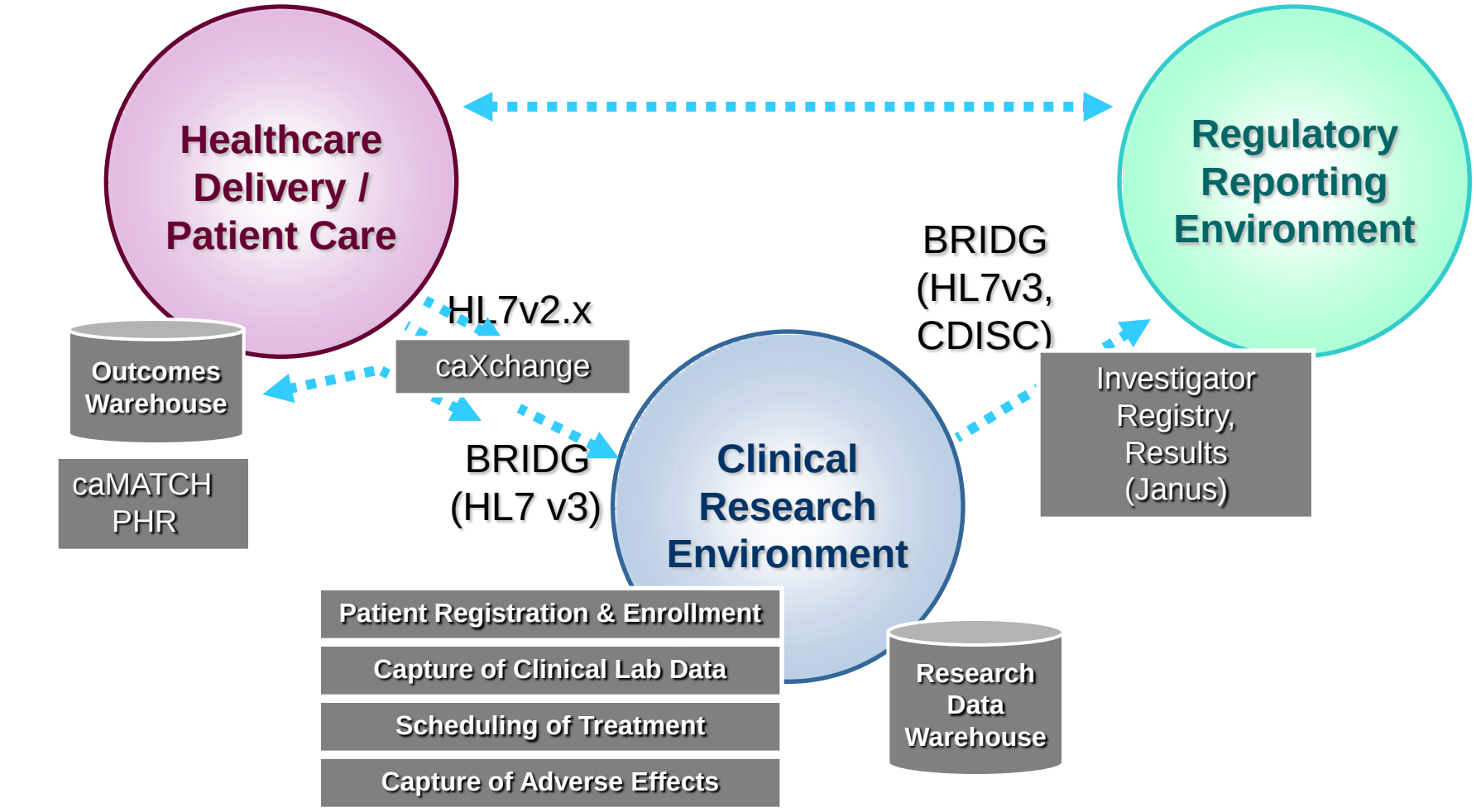
caBIG

A Common Healthcare Infrastructure



Standards allow information to be exchanged

A Common Healthcare Infrastructure



caBIG® tools provide functionality to enable a seamless continuum.

caBIG® Capabilities Enable

Discovery > Clinical Research > Clinical Care

Molecular Medicine

Clinical Research

Imaging

Molecular Biology

Pathology

caBIG

caBIG® Capabilities Enable

Discovery > Clinical Research > Clinical Care

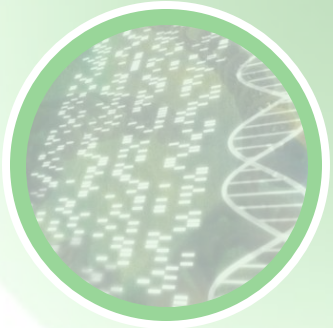
- Track clinical trial registrations
- Facilitate automatic capture of clinical laboratory data
- Manage reports describing adverse events during clinical trials

- Combine proteomics, gene expression, and other basic research data
- Submit and annotate microarray data
- Integrate microarray data from multiple manufacturers and permit analysis and visualization of data

Molecular Medicine

Clinical Research

Imaging



Molecular Biology

Pathology

- Utilize the National Cancer Imaging Archive repository for medical images including CAT scans and MRIs
- Visualize images using DICOM-compliant tools
- Annotated Images with distributed tools

- Access a library of well characterized, clinically annotated biospecimens
- Use tools to keep an inventory of a user's own samples
- Track the storage, distribution, and quality assurance of specimens

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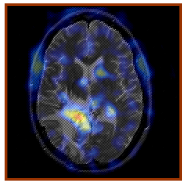
Case Study: The Cancer Genome Atlas (TCGA)

Connecting multiple sources, experiments, and data types

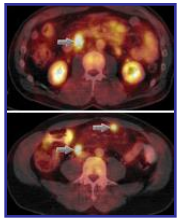
Three forms of cancer

glioblastoma multiforme (brain)



squamous carcinoma (lung)

serous cystadenocarcinoma (ovarian)

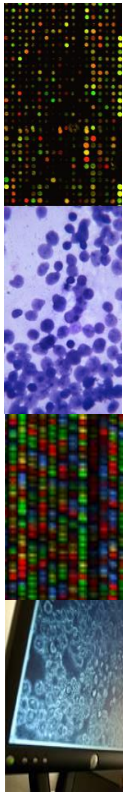


12 Organizations

- Biospecimen Core Resource
- 7 Cancer Genomic Characterization Centers
- 3 Genome Sequencing Centers
- Data Coordinating Center

Multiple data types

- Clinical diagnosis
- Treatment history
- Histologic diagnosis
- Pathologic status
- Tissue anatomic site
- Surgical history
- Gene expression
- Chromosomal copy number
- Loss of heterozygosity
- Methylation patterns
- miRNA expression
- DNA sequence



National Cancer Institute

National Human Genome Research Institute

Empowering researchers to integrate increasingly complex layers of cancer biology, from gene to clinical phenotype, as a whole

Gene ⟷ Genome ⟷ Genomes ⟷ Pathways ⟷ Clinical Outcomes

All from their computer

A single web-based portal for all analyses **– http://cma.nci.nih.gov**

National Cancer Institute

Context: TCGA

caBIG™ cancer Biomedical Informatics Grid ™

Cancer Molecular Analysis Portal

Gene View

Genome View

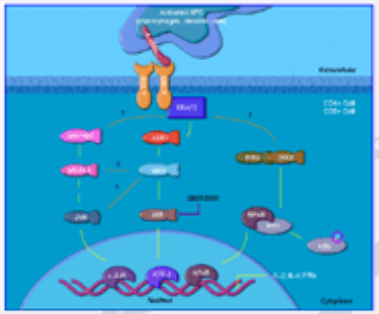
Clinical View

Analysis Tools

Gene View

Visualize gene expression, copy number, SNP, and pathway data on a gene by gene basis. Generate detailed study related reports for a given gene.

Available resources include: Gene Expression Plots, KM Survival Plots, CGWB Integration, and Pathway Visualizations.



Existing Users:

user:

pass:

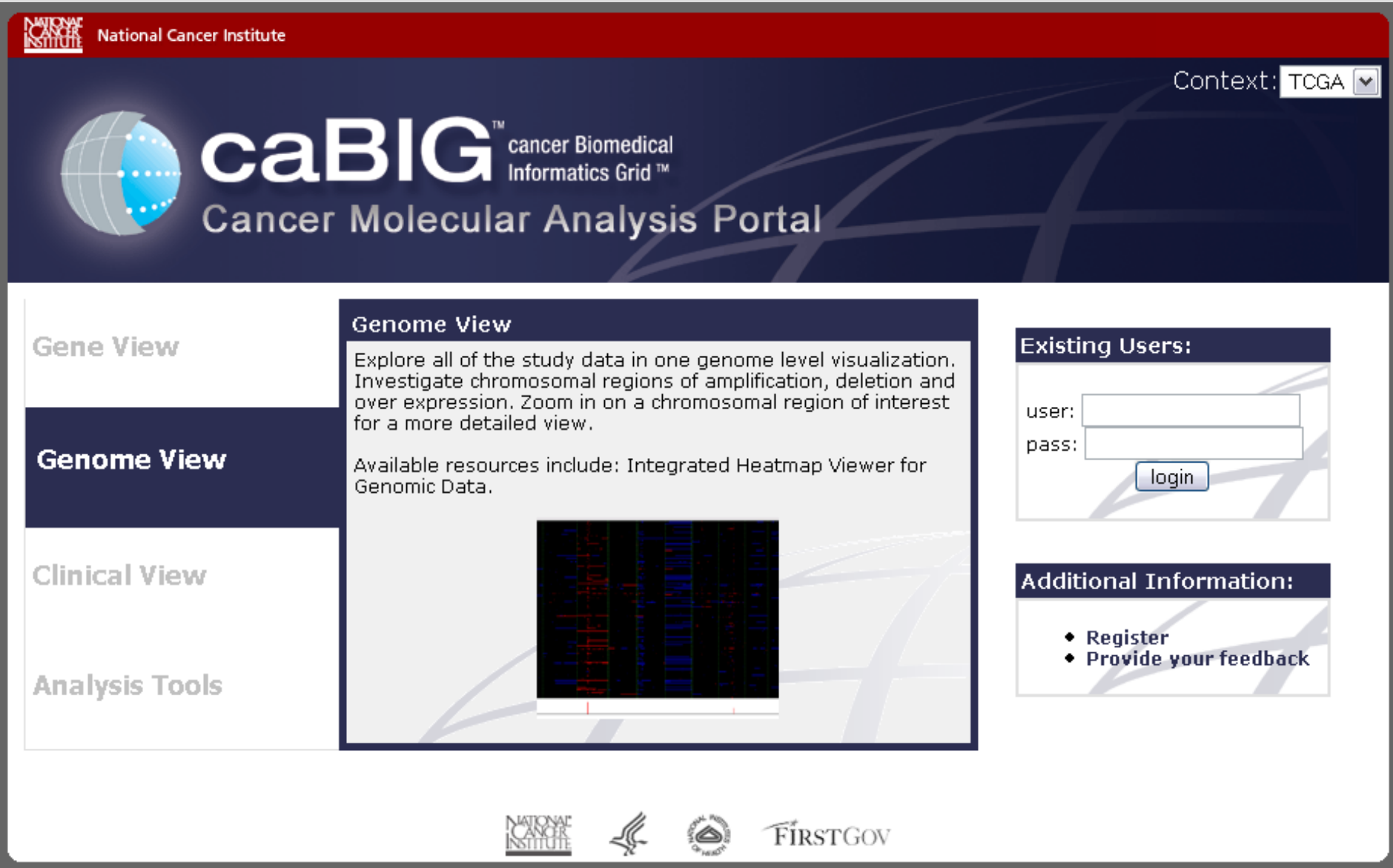
login

Additional Information:

- Register
- Provide your feedback

NATIONAL CANCER INSTITUTE · FIRSTGOV

A single web-based portal for all analyses **– http://cma.nci.nih.gov**



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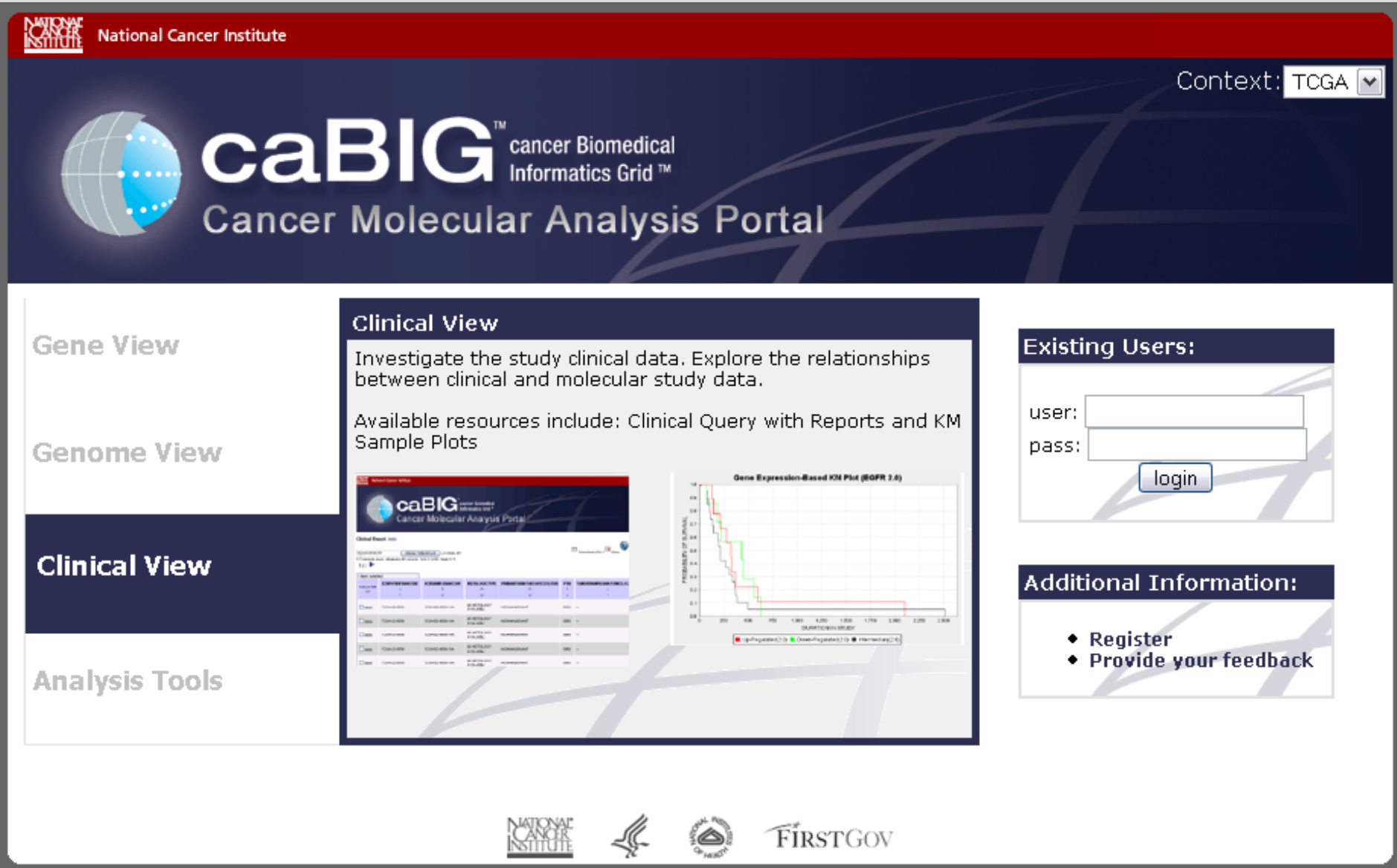

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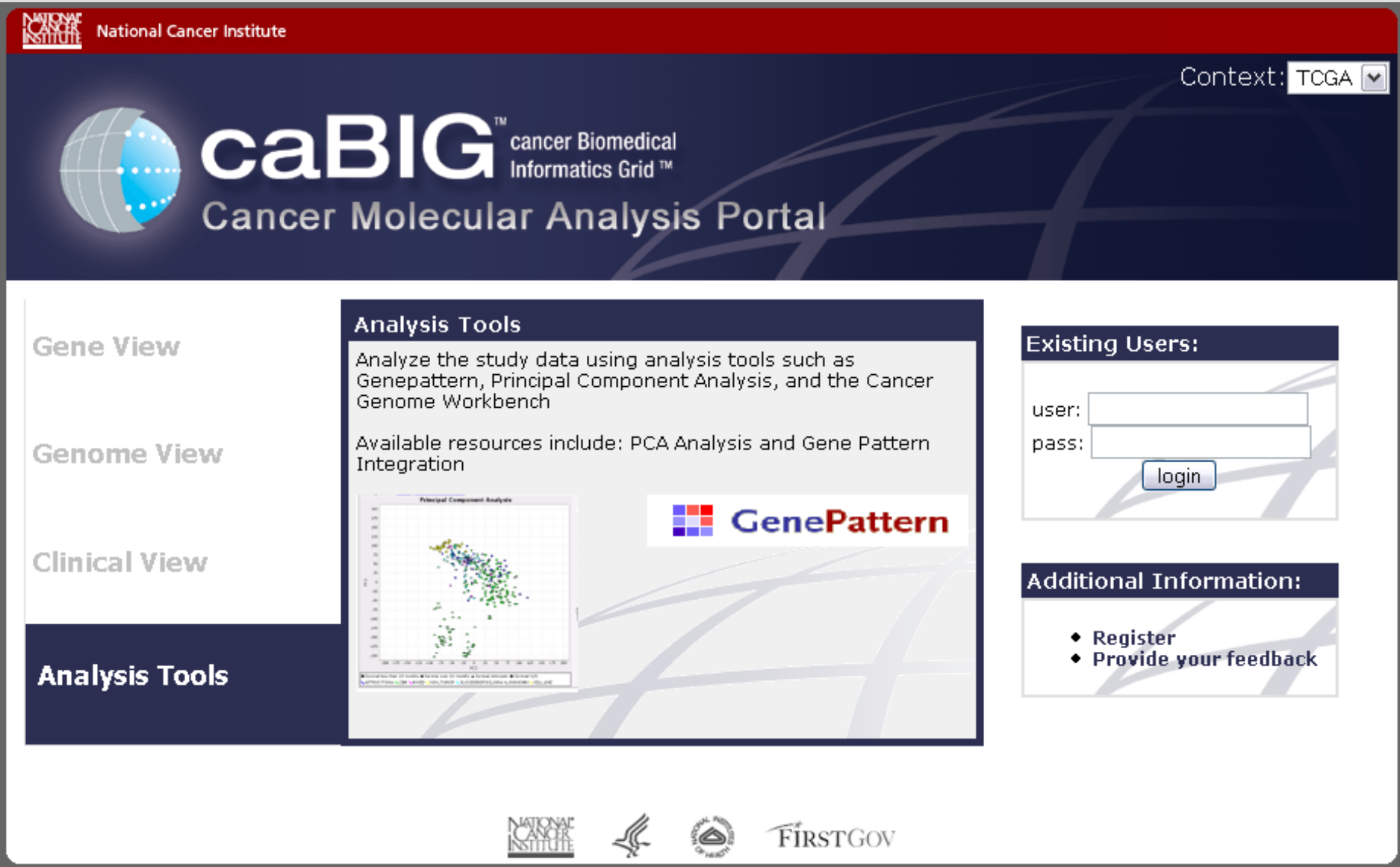

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Case Study: Interagency Oncology Task Force (IOTF)

IOTF: FIREBIRD

- **F**ederal **I**nvestigator **Re**gistry for **B**iomedical **I**nformatics **R**esearch **D**ata
- Automating and centralizing the 1572 registration process
- Enabling investigators to register online with NCI and other sponsors, including commercial sector
- Leveraging SAFE (“Signatures and Authentication For Everyone”) standard for legally enforceable digital signatures
- Developing a standard for 1572 information

FIREBIRD – FDA/NCI Collaboration

- Requirements definition – NCI works with FDA document management/compliance experts from:
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Drug Evaluation and Research (CDER)
  - Center for Devices and Radiological Health (CDRH)
- NCI delivered documentation of FDA module requirements, ratified with FDA the requirements for:
  - FDA inspection detail management
  - Biomedical Information abstraction (Forms FDA 1571 and 1572)

FIREBIRD Snapshot

- **Organizations (Practice Sites, Institutions) – 7829 available**
- **Labs – 202703 available**
  - FIREBIRD lab data is provided by quarterly uploads from Center for Medicare and Medicaid Services, including CLIA, CAP, and New York State
  - FIREBIRD leverages a distributed workload model, requiring any non-CLIA lab to have a certification attached to the lab record. The first user of a lab must upload the certification, a subsequent user may then find that certification already attached
- **Institutional Review Board – 5806 available**
  - FIREBIRD IRB data is provided via 6 hour syncs with the Office of Human Research Protection's IRB database
- **Medical License – Links to online licensure information are provided for all states and the District of Columbia (when available)**

Janus

Janus

- **An infrastructure that will:**
  - allow secure transmission of clinical research information between sponsors, researchers, and regulatory authorities
  - facilitate the adoption of electronic data standards, standardized terminologies, e-transactions, and e-submissions
  - reduce the overall cost of existing information gathering and submissions development processes as well as review and analysis of information; and
  - be accessible to all.

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cancer Biomedical Informatics Grid®

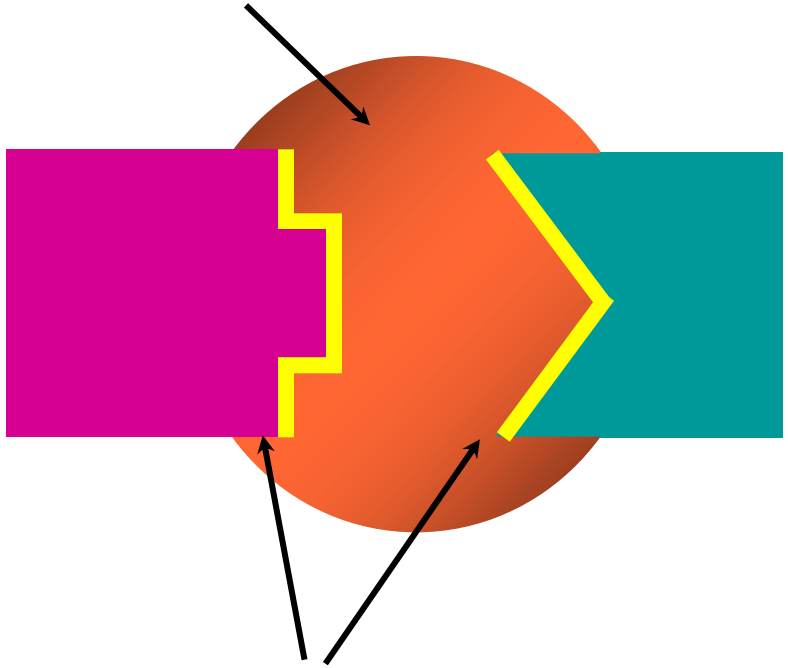
caBIG®: an open SOA with shared community semantics

Boundaries and Interfaces

- **Focus on boundaries and interfaces, how things fit together, not on the internal details**

- **Once they're built: assume that will be diverse & changing**

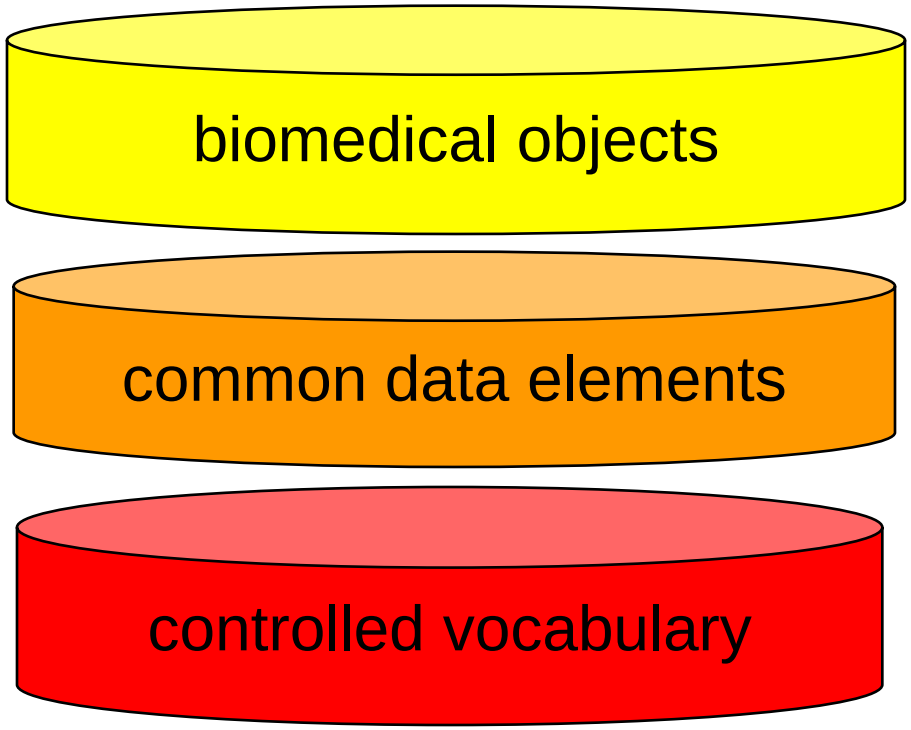
The glue that binds parts together is middleware infrastructure



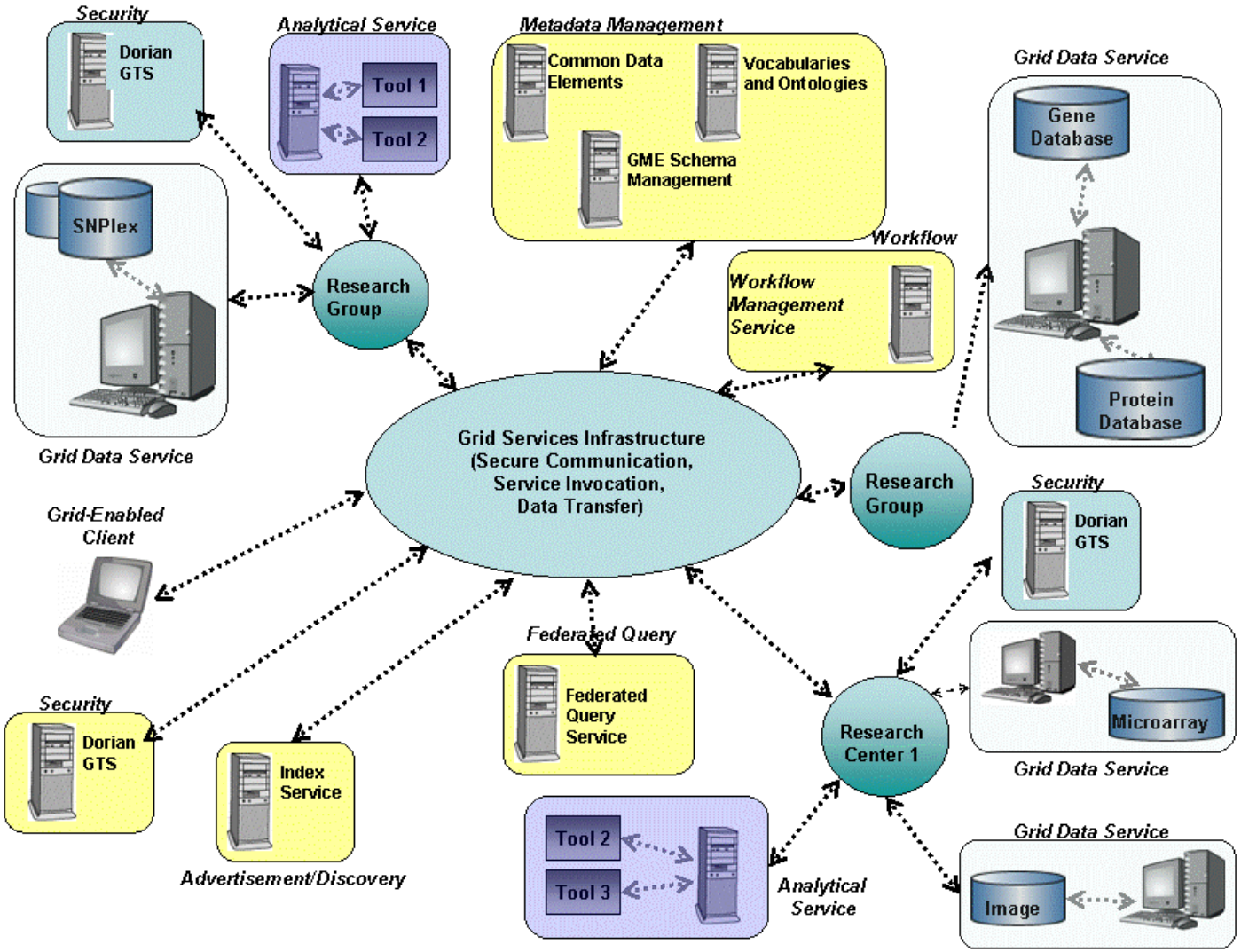
Shape of boundary is defined in APIs

Standards-Based Interoperability: caCORE

- **Community driven**
- **Dynamic implementation**
  - Built to be upgraded as standards “harden”, and domains expand



caGrid 1.1 Conceptual View



Connected with caBIG®

caBIG® adoption is unfolding in:

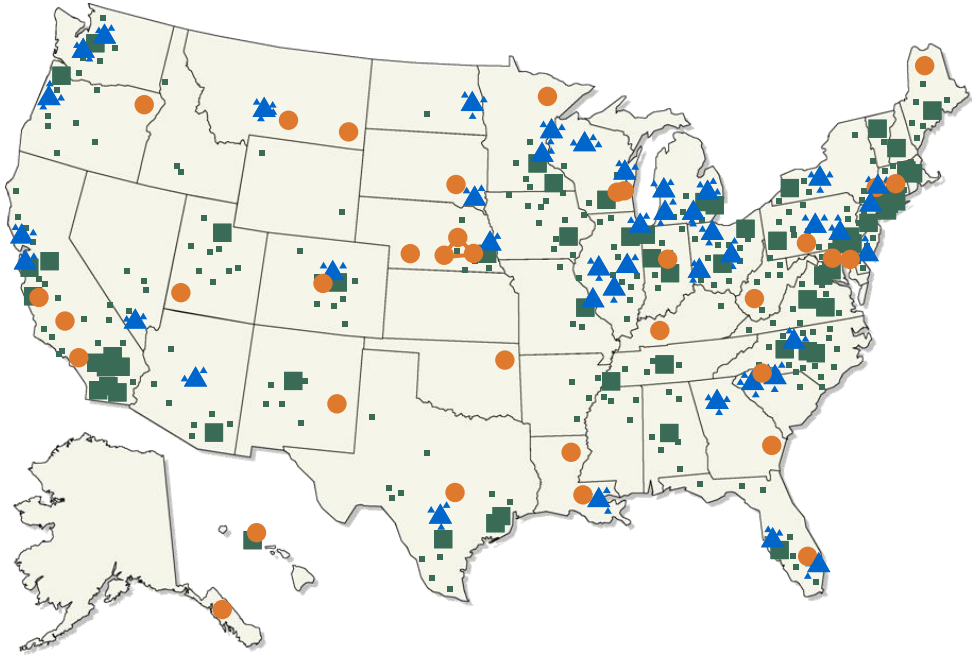
- 56 NCI-designated Cancer Centers
- 16 NCI Community Cancer Centers

caBIG® being integrated into federal health architecture to connect **National Health Information Network**

Global Expansion

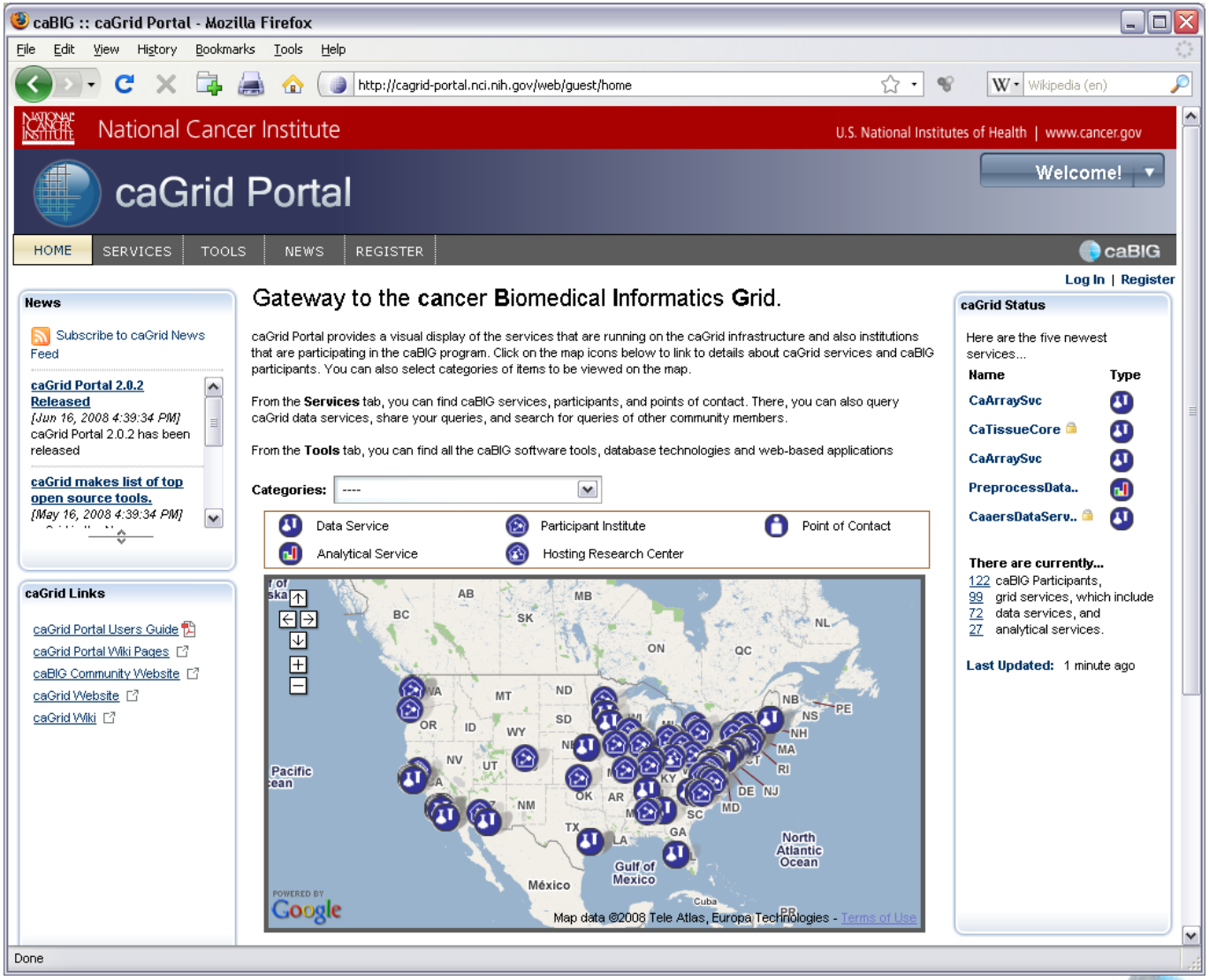
- United Kingdom
- China
- India
- Latin America

NCI-Designated Cancer Centers, Community Cancer Centers, and Community Oncology Programs

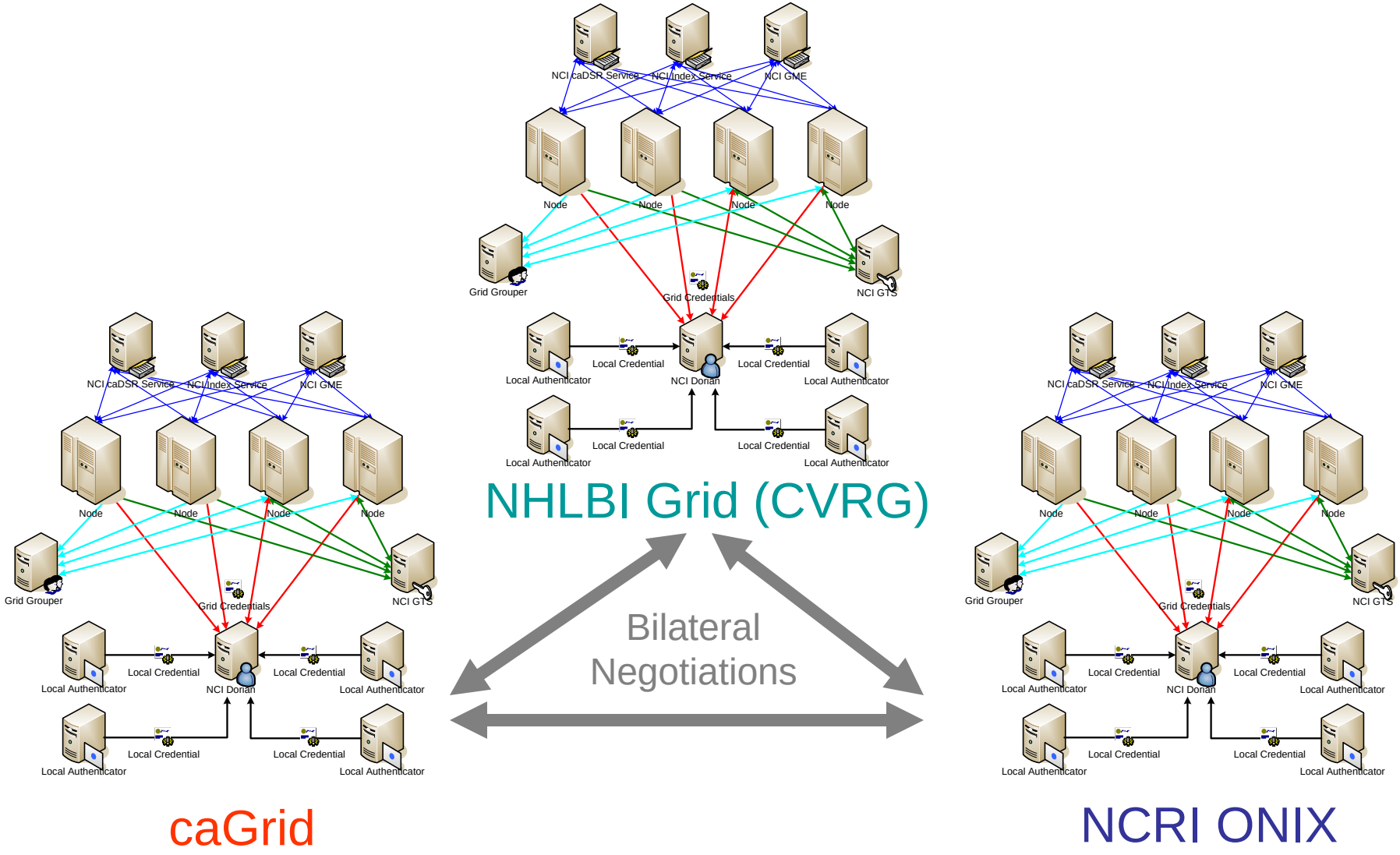


caBIG

caBIG® Snapshot



Grid of Grids…



caBIG® - The Next Wave:
Reaching End Users

caBIG® Installation Support

- A software packaged to facilitate installation including on-lineTutorials and Videos and Learning Center materials

Knowledge Centers – Power to the People

- A one-stop shop for domain expertise, technical and end-user documentation, training materials, and comprehensive, up-to-date installation packages for caBIG® tools
- A centralized site providing administration of open source development of caBIG® tools, collection and monitoring of defect reports, feature requests, and end-user requirements

Licensed Support Service Providers – Helping Hands

- Organizations that provide hands-on deployment support, customization, help desk, documentation development and end-user training

A Systems Approach:
BIG Health Consortium™

*"The world we have created today has problems which cannot be solved by thinking the way we thought when we created them."**

**Albert Einstein*

BIG Health Consortium™

Vision:

A biomedical system that synergizes the capabilities of the entire community to realize the promise of personalized medicine

Mission:

The BIG Health Consortium™ is a collaboration among stakeholders in biomedicine, including ***government, academe, industry, non-profit, and consumers,*** who come together in a novel organizational framework ***to demonstrate the feasibility and benefits of the personalized medicine paradigm***.

Strategy:

Through a series of personalized medicine **demonstration projects**, with an expanding number of collaborators, BIG Health will **bootstrap** a new approach in which clinical care, clinical research, and scientific discovery are linked.

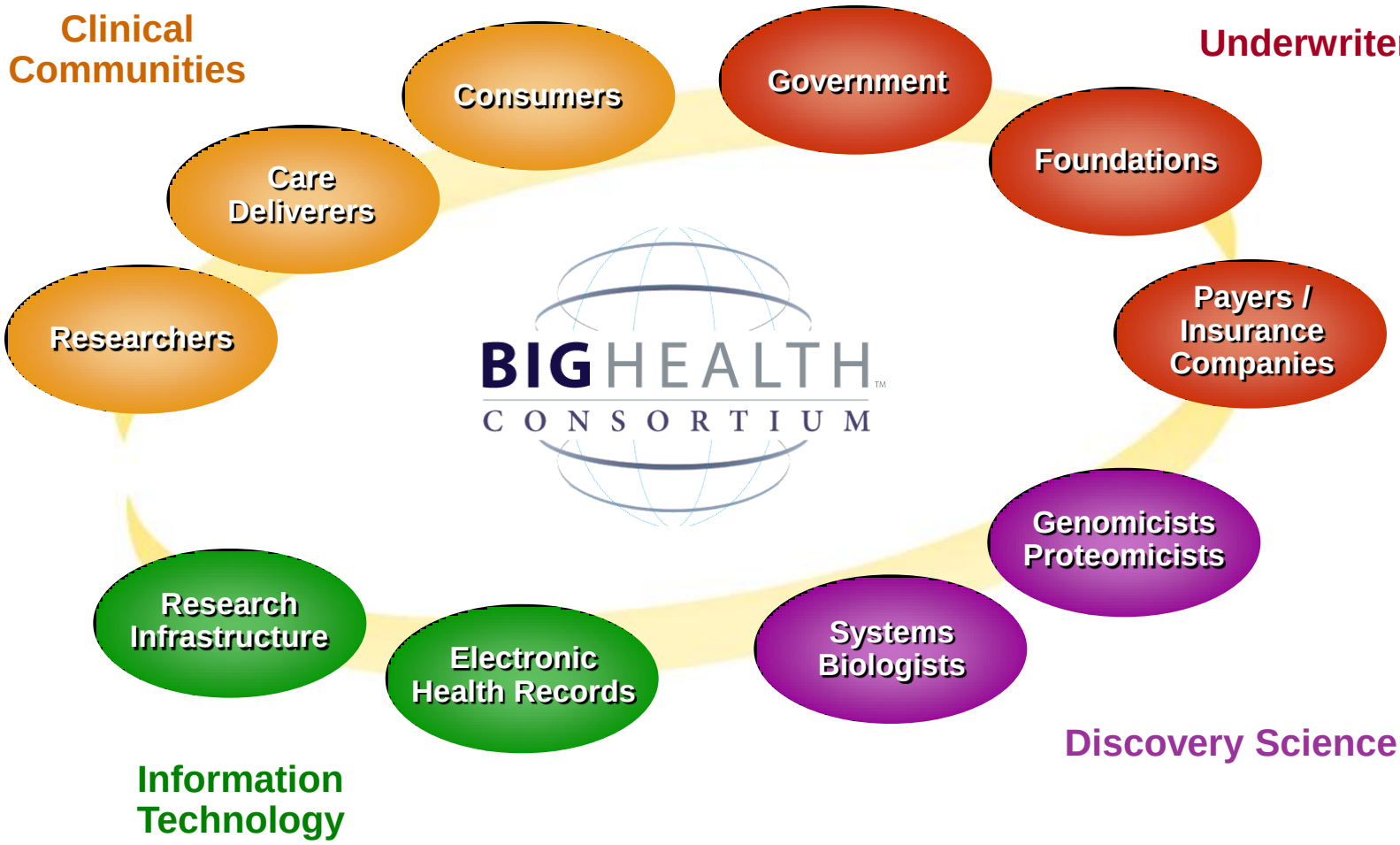
BIG Health Goals

BIG HEALTH CONSORTIUM

BIG Health will demonstrate that:

- Loosely-coupled sectors within life sciences and health care can come together in an ecosystem to implement personalized medicine real-world projects, in real time.
- The tools, infrastructure and standards of NCI's informatics infrastructure (caBIG®) can be applied to linking this ecosystem.
- Such an ecosystem can be financially self-sustaining.
- ***Clinical care, clinical research, and scientific discovery can be connected in a seamless continuum that speeds innovation and benefits patients.***

BIG Health Ecosystem



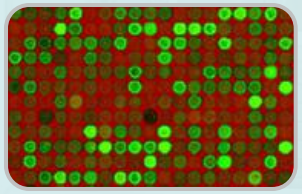
Research

Participants

Patients join research networks, grant consent, agree to be “sought” and to enroll – “on-demand” participants

Biospecimen Collections

Researchers can access and query large collections of well-characterized, clinically annotated specimens



Discovery of Correlations

Biomarkers are identified and validated; disease sub-groups emerge

BCM
Baylor College of Medicine

Individualization of Treatment

Patients are identified by sub-groups and treated appropriately

BIG HEALTH CONSORTIUM

Clinical Practice

Electronic Health Records

EHRs can connect to clinical trials in hospital settings

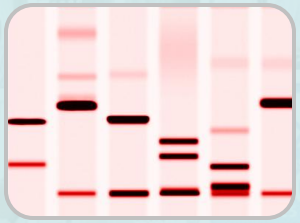
Research Finding Knowledgebases

Large-scale databases of latest research findings are connected to health delivery encounter

Learning Healthcare System

Local and national clinical encounter information is fed back to care providers to help inform clinical decision making

Consumer



My Genomic Profile

Consumers get their genetic and predisposition risk information

My Prevention Strategies

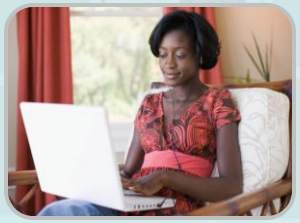
Consumers work with genetic counselors; coordinate with health care provider

My Clinical Record

Consumers link to their clinical histories with genetic profiles; access clinical research; participate in volunteer networks

BIG HEALTH CONSORTIUM

Standards



Interoperability

Data Sharing

caGRID

Connectivity

BIG HEALTH CONSORTIUM

BIG Health Ecosystem

Academic/Health Care Delivery

- Baylor College of Medicine
- Duke
- Georgetown
- Institute of Medicine
- NCCCP
- UCSF

Diagnostic

- Cellpoint
- Genzyme Genetics
- Monogram Biosciences

(Bio)Pharmaceutical

- Novartis
- Exelixis
- Genzyme
- J&J

IT/EHR/PHR

- Cerner
- Health IT Inc.
- Microsoft
- Oracle
- IBM

Foundations/Non-Profit/Advocacy

- Brookings Institution
- Canyon Ranch Institute
- CollabRx
- Critical Path Institute
- *FasterCures*
- Lance Armstrong Foundation
- Personalized Medicine Coalition

Health Care Consultancy

- Booz Allen Hamilton
- Feinstein Kean Healthcare
- Deliotte

Government

- CDC
- HHS Personalized Health Care Initiative
- NCI
- ONC

Payers

- Kaiser Permanente

Venture Capital

- Health Evolution Partners
- MDV

Personal Genomics

- Navigenics
- 23 and Me

http://BIGHealthConsortium.org

Opportunities for the FDA and BIG

- **Utilize “the grid”**
- **Add new data**
- **Add new services**
- **Add capacity**
- **Create an FDA Grid**
- **http://caBIG.cancer.gov**
- **http://caBIG.nci.nih.gov**

caBIG® : Power of Connection